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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,813	01/03/2002	Lawrence M. Boyd	4002-2734	1340

7590

11/16/2004

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EXAMINER

COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

23

Office Action Summary	Application No. 09/869,813	Applicant(s) BOYD ET AL.	
	Examiner David Comstock	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,17-37,40,41,44-47,50-52,54,56 and 58 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1,2,5-15,17-37,40,41,44-47,50-52,54,56 and 58 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 03 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-13, 18, 19, 40, 41, 44-47, 50, 51, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Zdeblick et al. (5,669,909).

Zdeblick et al. disclose a pair of interbody fusion devices 10 comprising an elongated generally cylindrical body having end walls 12 and 17, a side wall 16, and a hollow interior chamber 15 between the two ends (Fig. 2). One end 12 has flat discontinuities corresponding to discontinuities 22 in the side wall. The discontinuities allow the device to be nested against another device in a single disc space (see Fig. 6 and col. 7, lines 50-58). The side wall discontinuity extends along a length of the body aligned with the end wall discontinuity. The side wall discontinuity defines a plurality of side wall openings 24,25 to the interior chamber 15. The interbody fusion device 10 is formed of metal (see col. 5, lines 42-47). The outer surface defines threaded bone-engaging portions 18. The device includes a tool-engaging end 13 defining a tool

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engaging hole, e.g. a hex recess (see col. 7, lines 6-10). An osteogenic material is disposed within the chamber (see col. 5, lines 55-59 and col. 7, lines 50-58). Each side wall discontinuity appears to extend over approximately 25% of the circumference of the body (see Attachment A, corresponding to Fig. 4). The side wall discontinuity appears to extend over at least 80% of the length of the body (see Fig. 2). Osteogenic material could be introduced through the openings 24,25. Zdeblick also discloses preparing adjacent vertebrae and placing the devices in the intervertebral space to nest against each other (see col. 7, lines 50-58 and col. 10, line 48 - col. 11, line 51 and Fig. 6). It is also disclosed to pack osteogenic material prior to or after implanting the devices, i.e. "additional bone graft material" where "additional" implies some was added before implantation while the "additional" amount was added "in situ" (see col. 5, lines 55-59 and col. 7, lines 50-58).

Claims 52 and 54-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Brosnahan, III (5,645,598; cited by applicant).

Brosnahan, III discloses a metal fusion spacer 10 comprising a generally cylindrical elongate body defining a side wall opening into an interior chamber 40 (see Fig. 14 and col. 4, lines 33-41). The first and second ends have a concave discontinuity 48,50. The side wall includes threads. The end walls are integrally fixed to the side wall. The spacer includes a tool-engaging end having a tool-engaging hole 32. The chamber is filled with an osteogenic material 42 (see col. 5, lines 31-45). The device includes the concave discontinuities to allow it to be closely nested with another implant (see col. 5, lines 46-62). The end walls have a profile defining a discontinuous arc

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44,46 extending around at least 180 degrees of the circle and comprise the two concave surfaces 48,50 (see Fig. 14).

Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Kohrs (6,224,631).

Kohrs discloses a fusion spacer 10 comprising a generally cylindrical elongated body 4,5 (see Figs. 1, 2, and 4). The first and second end walls have concave discontinuities 21,22 that extend across the length of the spacer to form side walls 8a,8b,8c,8d (and the portions 1,2 connecting the side wall components 8a,8b,8c,8d) connecting the first and second ends. The discontinuities in the side walls are at the same location as the discontinuities in the end walls and extend about the circumference of the device the same extent. The side walls define hollow interior cavities 9a,9b,9c. It is especially noted that hollow interior cavity 9b is located between the first and second ends of the body (see Fig. 1). The shape of the device renders it capable of being nested with another implant. The end walls have a profile defining a discontinuous arc extending around at least 180 degrees of the circle and comprise the concave surfaces 21,22 (see Fig. 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15, 17-37, 40, 41, 44-47, 50, 51, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (5,669,909) in view of Michelson (5,593,409; cited by applicant).

Zdeblick discloses the claimed invention except for the concave side wall and end wall discontinuities. Michelson discloses that flat side walls and concave side walls are functionally equivalent means of allowing two implants to fit within a single disc space (see Figs. 25 and 43, col. 12, line 59 - col. 13, line 3; and col. 15, lines 19-38). It would have been obvious to substitute concave side wall discontinuities for flat side wall discontinuities, in view of Michelson, as this would involve nothing more than the substitution of functionally equivalent means of accommodating two implants in a single disc space, known in the art at the time of the invention. With regard to claims 8 and 27 it also would have been obvious to form the osteogenic material of demineralized bone, a calcium phosphate, bioceramic, bioglass, an osteoinductive factor, or other known materials or mixtures thereof, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed 23 July 2004 have been fully considered but they are not persuasive, except insofar as they pertain to Michelson teaching against a threaded exterior surface.

In response to applicant's argument that Zdeblick et al. do not anticipate applicant's invention, it is noted that to be cylindrical, at least within a broadest reasonable interpretation, the implant need only relate to or resemble a cylinder, or a generally circular shape extruded to form a solid, and need not have any other specific characteristics with respect to this limitation. Here, the implant in fact is such a cylinder or at least more closely resembles or relates to the same than it does a cone, since a cone shape would need to continue to a pointed end. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP 2111.01.

In response to applicant's argument that the Brosnahan, III fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a side wall discontinuity having an opening in communication with an interior cavity or chamber in the spacer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is noted that claim 52 does not necessarily require that the "discontinuities" (defined by the arc) have the opening in communication with the interior cavity or chamber.

In response to applicant's argument that Kohrs does not anticipate applicant's invention, it is noted that the openings 9b can be considered "chambers" at least within a broadest reasonable interpretation, since they occupy a significant width of the implant and they occupy a space that is at least enclosed about a periphery thereof, as bounded by the arms 8a-c on the side and the implant body 1 and 2 on the top and bottom (see e.g. Fig. 1). The test for interpreting a reference is what the reference as a whole would have suggested to one of ordinary skill in the art. *In re Sheckler*, 168 USPQ 716 (CCPA 1971); *In re McLaughlin*, 170 USPQ 209 (CCPA 1971); *In re Young*, 159 USPQ 725 (CCPA 1968). With regard to the meaning of chamber, it is noted that applicant's specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP 2111.01. Furthermore, it is noted that the implants are capable of nesting, one within another, at least to some degree and at least within a broadest reasonable interpretation, since the convex portions of the sidewalls of one implant can at least fit within the space created by the discontinuities in another such implant. Furthermore, the exact meaning of "substantially" is not defined by applicant and cannot be given any more weight than its plain meaning which comprises a construction of "approximately." Again, it is noted that applicant's specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is

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not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP 2111.01.

In response to applicant's argument that Michelson does not render obvious applicant's invention, it is noted that whether Michelson teaches or teaches away from external threads is irrelevant, since here, Michelson is being relied upon, not in any way for its teachings regarding threads, but rather, for its distinct teachings regarding concave side walls, as set forth in the rejection. It is noted that a reference must be considered in its entirety for what it would have suggested to one of ordinary skill in the art. *In re Sheckler*, 168 USPQ 716 (CCPA 1971); *In re McLaughlin*, 170 USPQ 209 (CCPA 1971); *In re Young*, 159 USPQ 725 (CCPA 1968).

Conclusion

Applicant's amendment incorporating threads into the independent claims necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

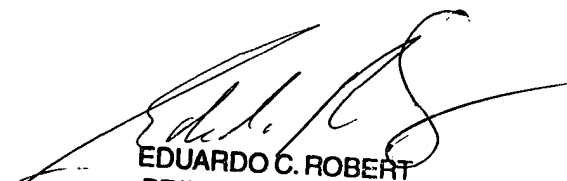
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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.



D. Comstock
08 November 2004



EDUARDO C. ROBERT
PRIMARY EXAMINER